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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

08/470,735 06/06/95 ISRAELI

R 41426-D/JPW/

EXAMINER

HM22/0214

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GUCKER, S
ART UNIT PAPER NUMBER

1647
DATE MAILED:

29
02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/470,235

Applicant(s)

Cheneli et al.

Examiner

Stephen Tucker

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/27/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 114-118 & 120-126 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 114-118 & 120-126 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 24, 25, & 27
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1647

Response to Amendment

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 114-118 and 120-122 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The antibodies claimed are products of nature and do not show the hand of man. Amending the claims to recite an isolated or purified antibody would obviate the grounds of this rejection.
5. Claims 114-118 and 120-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner was unable to find a definition for "an outside region of" prostate specific membrane antigenic polypeptide in the specification. Given the disclosure on pages 53-54 of only a membrane spanning domain, an "outside region" could be interpreted as being either the inner or outer membrane domain of the PSM antigen as described on page 54 because either domain is outside of the transmembrane domain which appears to be

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the only domain specifically identified in the specification, i.e. the Examiner could not find in the instant specification any teachings as to the orientation of the PSM antigen other than the disclosure of a membrane spanning domain. Given the lack of teaching as to the PSM antigen's orientation in the cell, i.e. to the location of the N- or C-terminal as being intracellular or extracellular, the new limitation of "an outside region of" is vague and indefinite for not distinguishing between the inner and outer membrane domains of PSM antigen. The grounds of this rejection could be obviated by amending the claims to correspond to the language of page 54, line 5, which describes "an outer membrane domain[s] of the PSM antigen".

Claims 114-118 are also rejected as being vague and indefinite because they recite transitional language which could be interpreted to relate back to the antibody or the PSM antigen. For instance, in claim 114, the subject of "comprising a fragment of the prostate specific membrane antigen having within its structure..." could be interpreted as either the antibody or the PSM antigen as the claim is currently worded. It is suggested that the claims be amended to recite wording along the lines of: --An antibody which binds to an outer membrane domain of prostate specific membrane antigenic polypeptide wherein said outer membrane domain comprises a fragment of the prostate specific membrane antigen having within its structure the consecutive amino acid sequence...--.

6. Claims 114-118 and 120-126 are rejected under 35 U.S.C. 102(e) as anticipated by Horoszewics, Horoszewics discloses 7E11-C5, a monoclonal antibody that binds to PSMA (column 11, lines 27-56 and column 12, lines 31 to column 13, line 12) which meet all the

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limitations of the instant claims because of the inherency of SEQ ID NO:2 to PSMA. In addition, the open language of claim 121 and the recitation of the outside region is anticipated by Horoszewics.

Applicant's arguments filed 2/12/01 have been fully considered but they are not persuasive because the Examiner was unable to find a definition for "an outside region of" prostate specific membrane antigenic polypeptide in the specification. Given the disclosure on pages 53-54 of only a membrane spanning domain, an "outside region" could be interpreted as being either the inner or outer membrane domain of the PSM antigen as described on page 54 because either domain is outside of the transmembrane domain which appears to be the only domain specifically identified in the specification, i.e. the Examiner could not find in the instant specification any teachings as to the orientation of the PSM antigen other than the disclosure of a membrane spanning domain. Given the lack of teaching as to the PSM antigen's orientation in the cell, i.e. to the location of the N- or C-terminal as being intracellular or extracellular, the new limitation of "an outside region of" cannot be used to exclude the prior art of record. The grounds of this rejection could be obviated by amending the claims to correspond to the language of page 54, line 5, which describes "an outer membrane domain[s] of the PSM antigen".

7. Claims 120-122 are rejected under 35 U.S.C. 102(b) as anticipated by Feng et al. 1991. Feng et al discloses of an isolated PSM antigen with a molecular weight of 100 kda and a monoclonal antibody which reacts with said antigen.

Applicant's arguments filed 6/17/99 have been fully considered but they are not persuasive. Applicant argues that the declarations of Kaladas, Rodwell, and Horoszewicz establish that the Feng reference is not enabling due to the lack of public availability of the 7E11-C5 hybridoma cell line. However, the 102(b) statute above clearly states that if the invention was described in a printed publication or in public use, the statute would apply. It is not required that the invention be described and be in public use. Regarding Applicant's arguments that the disclosure of the specific 7E11-C5 antibody should not anticipate a genus claim, since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments and declarations filed 3/2/00 have been fully considered but they are not persuasive because Applicant argues that 7E11-C5 and its antigen were not publicly available. However, the Examiner maintains the position that the instant invention was described in a printed publication which meets the statutory limitations.

Applicant's arguments filed 2/12/01 have been fully considered but they are not persuasive because the Examiner was unable to find a definition for "an outside region of" prostate specific membrane antigenic polypeptide in the specification. Given the disclosure on pages 53-54 of only a membrane spanning domain, an "outside region" could be interpreted as

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being either the inner or outer membrane domain of the PSM antigen as described on page 54 because either domain is outside of the transmembrane domain which appears to be the only domain specifically identified in the specification, i.e. the Examiner could not find in the instant specification any teachings as to the orientation of the PSM antigen other than the disclosure of a membrane spanning domain. Given the lack of teaching as to the PSM antigen's orientation in the cell, i.e. to the location of the N- or C-terminal as being intracellular or extracellular, the new limitation of "an outside region of" cannot be used to exclude the prior art of record. The grounds of this rejection could be obviated by amending the claims to correspond to the language of page 54, line 5, which describes "an outer membrane domain[s] of the PSM antigen".

8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0830 to 1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

February 12, 2001

Gary L. Kunz
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